Notice of Allowability	Application No.	Applicant(s)	
	09/928,457	NASSIF ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *9/2/2004*.

2. ☒ The allowed claim(s) is/are *69,89 and 106-111; now claims 1-8*.

3. ☒ The drawings filed on *14 August 2001* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *9/2/2004* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

L. R. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: Amened and new claims directed to an isolated DNA that will hybridize to SEQ ID NO 95, under high stringency, and only hybridize to Neisseria meningitides and Neisseria gonorrheae, and not Neisseria lactamica strain NI8064, is not taught nor reasonably suggested in the prior art of record and therefore defines allowable subject matter.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. B.J. Sadoff, Registration Number 36,663 on September 2, 2004. The application has been amended as

follows:

AMENDMENTS TO THE CLAIMS:

Amend the claims as follows:

Claims 1-68, 70-88, and 90-105. (Canceled)

69. (Proposed Currently Amended) An isolated DNA which is specific to *Neisseria meningitidis* (Nm) and *Neisseria* gonorrheae (Ng), and hybridizes on a Southern blot to SEQ ID NO:95 and does not hybridize on a Southern blot to a DNA sequence of *Neisseria lactamica* (Nl) strain Nl8064, under the following hybridization conditions: 18 h at 65°C, with a solution comprising 0.5 M $NaPO_4$ ~~0.5 M~~ pH 7.2, ~~pH 7.2~~; 0.001 M EDTA-Na ~~0.001 M, 1%,~~ 1% bovine serum albumin and 7% sodium dodecylsulphate, followed by at least two washes in a solution comprising 40 mM Na PO_4 ~~40 mM~~ pH 7.2, 1mM EDTA, and 1% SDS/EDTA ~~1 mM/SDS 1%~~, the final wash being conducted at 65°C for 5 minutes, or the complement of said isolated DNA which is specific to *Neisseria meningitidis* (Nm) and *Neisseria* gonorrheae (Ng),

provided that said DNA or the complement of said isolated DNA is not *pilC*, or a gene involved in the biosynthesis of any one of the polysaccharide capsule, IgA proteases, pilin, a protein which binds transferrin, a protein which binds lactoferin, and an opacity protein

said DNA being within an islet involved in the colonization of the nasopharynx or invasion of the submucousal space or systemic dissemination of Nm.

89. (Proposed Currently Amended) A composition comprising ~~a~~ the DNA or complement of claim 69 and a carrier.

106. (Proposed Currently Amended) An isolated DNA which is specific to *Neisseria meningitidis* (Nm) and *Neisseria* gonorrheae (Ng), and hybridizes on a Southern blot to SEQ ID NO:85 and does not hybridize on a Southern blot to a DNA sequence of *Neisseria lactamica* (Nl) strain NI8064, under the following hybridization conditions: 16 h at 65°C, with a solution comprising 0.5 M $NaPO_4$ ~~0.5 M~~, pH 7.2, 0.001 M EDTA-Na, ~~; EDTA-Na 0.001 M, 1%,~~ 1% bovine serum albumin and 7% sodium dodecylsulphate, followed by at least two washes in a solution comprising 40 mM Na PO_4 ~~40 mM~~ pH 7.2~~/EDTA 1 mM/SDS 1%~~, 1 mM EDTA and 1% SDS, the final wash being conducted at 65°C for 5 minutes, or the complement of said isolated DNA which is specific to *Neisseria meningitidis* (Nm) and *Neisseria* gonorrheae (Ng),

provided that said DNA or the complement of said isolated DNA is not *pilC*, or a gene involved in the biosynthesis of any one of the polysaccharide capsule, IgA proteases, pilin, a protein which binds transferrin, a protein which binds lactoferin, and an opacity protein.

107. (Proposed Currently Amended) A composition comprising ~~a~~ the DNA or complement of claim 106 and a carrier.

108. (new) A method of detecting *Neisseria meningitidis* (Nm) or *Neisseria* gonorrheae (Ng) in a sample from a patient, said method comprising providing isolated sample DNA of said sample from the patient, contacting said sample DNA with the

isolated DNA of claim 69, said contacting being performed under conditions which allow hybridization of said sample DNA and said isolated DNA, and detecting any hybridization of said sample DNA and said isolated DNA, such that said hybridization of said sample DNA and said isolated DNA specifically indicates the presence of said Nm or Ng in said sample,

wherein said isolated DNA is specific to Nm and Ng and does not hybridize on a Southern blot to a DNA sequence of *Neisseria lactamica* (Nl) strain NI6054 under the following hybridization conditions: 16 h at 65°C, with a solution comprising 0.5 M $NaPO_4$ pH 7.2, 0.001 M EDTA-Na, 1% bovine serum albumin and 7% sodium dodecylsulphate, followed by at least two washes in a solution comprising 40 mM Na PO_4 pH 7.2, 1mM EDTA, and 1% SDS, the final wash being conducted at 65°C for 5 minutes, and

wherein said isolated DNA specifically hybridizes to Nm DNA and Ng DNA in the presence of Nl DNA.

108. (new) A method of detecting *Neisseria meningitidis* (Nm) or *Neisseria gonorrhoae* (Ng) in a sample from a patient, said method comprising providing isolated sample DNA of said sample from the patient, contacting said sample DNA with the composition of claim 69 under conditions which allow hybridization of said sample DNA and DNA in said composition, and detecting any hybridization of said sample DNA and said DNA in said composition, such that said hybridization of said sample DNA and said DNA in said composition specifically indicates the presence of said Nm or Ng in said sample,

wherein said DNA in said composition is specific to Nm and Ng and does not hybridize on a Southern blot to a DNA sequence of *Neisseria lactamica* (Nl) strain NI8084 under the following hybridization conditions: 16 h at 65°C, with a solution comprising 0.5 M $NaPO_4$ pH 7.2, 0.001 M EDTA-Na, 1% bovine serum albumin and 7% sodium dodecylsulphate, followed by at least two washes in a solution comprising 40 mM Na PO_4 pH 7.2, 1mM EDTA, and 1% SDS, the final wash being conducted at 65°C for 5 minutes, and

wherein said DNA is said composition specifically hybridizes to Nm DNA and Ng DNA in the presence of Nl DNA.

110. (new) A method of detecting *Neisseria meningitidis* (Nm) or *Neisseria* gonorrheae (Ng) in a sample from a patient, said method comprising providing isolated sample DNA of said sample from the patient, contacting said sample DNA with the isolated DNA of claim 106, said contacting being performed under conditions which allow hybridization of said sample DNA and said isolated DNA, and detecting any hybridization of said sample DNA and said isolated DNA, such that said hybridization of said sample DNA and said isolated DNA specifically indicates the presence of said Nm or Ng in said sample,

wherein said isolated DNA is specific to Nm and Ng and does not hybridize on a Southern blot to a DNA sequence of *Neisseria lactamica* (Nl) strain NI8084 under the following hybridization conditions: 16 h at 65°C, with a solution comprising 0.5 M $NaPO_4$ pH 7.2, 0.001 M EDTA-Na, 1% bovine serum albumin and 7% sodium dodecylsulphate.

followed by at least two washes in a solution comprising 40 mM Na PO_4 pH 7.2, 1mM EDTA, and 1% SDS, the final wash being conducted at 65°C for 5 minutes, and

wherein said isolated DNA specifically hybridizes to Nm DNA and Ng DNA in the presence of NI DNA.

111. (new) A method of detecting *Neisseria meningitidis* (Nm) or *Neisseria* gonorrhoae (Ng) in a sample from a patient, said method comprising providing isolated sample DNA of said sample from the patient, contacting said sample DNA with the composition of claim 107 under conditions which allow hybridization of said sample DNA and DNA in said composition, and detecting any hybridization of said sample DNA and said DNA in said composition, such that said hybridization of said sample DNA and said DNA in said composition specifically indicates the presence of said Nm or Ng in said sample,

wherein said DNA in said composition is specific to Nm and Ng and does not hybridize on a Southern blot to a DNA sequence of *Neisseria lactamica* (NI) strain NI8084 under the following hybridization conditions: 16 h at 65°C, with a solution comprising 0.5 M $NaPO_4$ pH 7.2, 0.001 M EDTA-Na, 1% bovine serum albumin and 7% sodium dodecylsulphate, followed by at least two washes in a solution comprising 40 mM Na PO_4 pH 7.2, 1mM EDTA, and 1% SDS, the final wash being conducted at 65°C for 5 minutes, and

wherein said DNA in said composition specifically hybridizes to Nm DNA and Ng DNA in the presence of NI DNA.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
September 2, 2004